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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/502,498	02/11/00	KILIAN A	191106.407C2

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EXAMINER	
WALICKA,M	

ART UNIT	PAPER NUMBER
1652	8

DATE MAILED: 05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Offic Action Summary	Application N .	Applicant(s)	
	09/502,498	KILIAN ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *02/11/00 and 10/10/01* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-4, 6-7, 9-19, 22-29, 31-44, 46-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-4, 6-7, 9-19, 22-29, 31-44, 46-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

The examiner acknowledges the application and the preliminary amendment filed on February 11, 2000, as well as supplemental preliminary amendment filed on October 10, 2000 containing paper copy of the sequence listing. The amendments to the specification were entered as requested. Claims 5, 8, 20, 21, 30, 28, and 45 were deleted. Claims 3, 4, 6, 7, 9, 11, 13, 18, 27, 28, 29, 31, 33, 34, 36, 37, 44 and 53 were amended. Claims 1-4, 6, 7, 9-19, 22-29, 31-44, 46-64 are pending in the application.

Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1-15 and 61, drawn to DNA, expression vector and transformed host cell to produce recombinantly vertebrate telomerase, classified in class 435, subclass 252.3.

II. Claim 16-22, drawn to vertebrate telomerase, its variants and fragments, classified in class 435, subclass 194.

III. Claim 23-26, drawn to antibody and a hydridoma cell for their production, classified in class 530, subclass 387.9.

IV. Claim 27-40, drawn to the telomerase DNA probe, primers for amplification, and oligonucleotides that hybridize to telomerase gene, classified in class 536, subclasses 24.3 and 24.1.

V. Claim 41-44 and 48-49, drawn to a method of diagnosing cancer using telomerase cDNA, and a pattern of expression of telomerase RNA, classified in class 435, subclass 6.

VI. Claim 46 and 47, drawn to a method of determining a pattern of expression of telomerase RNA, classified in class 435, subclass 6.

VII. Claim 50-53, drawn to transgenic animals where the telomerase gene is operably linked to a promotor effective for the expression of the gene, classified in class 800, subclass 13.

VIII. Claim 54, drawn to a mouse having endogenous telomerase gene disrupted, classified in class 800, subclass 9.

IX. Claim 55-59, drawn to inhibitor of vertebrate telomerase, classified in class 435, subclass 184.

X. Claim 60, drawn to a method of treating cancer, comprising administering therapeutically effective amount of telomerase inhibitor, classified in class 514, subclass **?**.

XI. Claims 62-64 drawn to a method of identifying an effector of telomerase activity classified in class 536, subclass 184.

Inventions of Group I, II, III, IV and IX are unrelated because they are independent chemical entities that require independent search of the patent and non-patent literature.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. DNA encoding telomerase may have many other uses such as in a method to make telomerase antibodies.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. RNA expressed form the expression vector of invention I may be used in protein synthesis.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cloned DNA encoding telomerase and the transgenic animal containing said DNA are not disclosed as capable of use together. Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cloned DNA encoding telomerase and the mouse having endogenous telomerase gene disrupted are not disclosed as capable of use together.

Invention I and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cloned DNA encoding telomerase and the

method of treating cancer comprising administration therapeutically effective dose of inhibitor of telomerase activity are not disclosed as capable of use together.

Inventions I and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the cloned DNA encoding telomerase is not used in the method of identifying an effector of telomerase activity.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase and the method using telomerase cDNA for diagnosing cancer are not disclosed as capable of use together and have different modes of operation, different functions and different effects.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the telomerase and the method of determining a pattern of expression of telomerase RNA are not disclosed as capable of use together.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase and a transgenic animal containing DNA encoding said enzyme are not disclosed as capable of use together.

Inventions II and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase and mouse having endogenous telomerase gene disrupted are not disclosed as capable of use together.

Invention II and X are unrelated Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase and the method of treating cancer comprising administration therapeutically effective dose of inhibitor of telomerase activity are not disclosed as capable of use together.

Inventions II and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. the telomerase, may be used in a method to make antibodies.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibody that binds telomerase and the method of using telomerase cDNA for cancer diagnosis are not disclosed as capable of use together.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibody that binds telomerase is not used in the method of determining of a pattern of expression of telomerase RNA.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibody that binds telomerase and a transgenic animal containing said DNA are not disclosed as capable of use together.

Inventions III and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibody that binds telomerase and a mouse having endogenous telomerase gene disrupted are not disclosed as capable of use together.

Invention III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antibody that binds telomerase is not used in the method of treating cancer.

Inventions III and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibody that binds telomerase is not used in the method of identifying an effector of telomerase activity.

Inventions IV and V are related as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1)

the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. the telomerase DNA probe and primers may be used to *in vitro* hybridize to or amplify DNA telomerase from in normal cells.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase DNA probe, primers, and oligonucleotides and a method of determining a pattern of expression of telomerase RNA and its use for diagnosing cancer are not disclosed as capable of use together and have different modes of operation, different functions and effects.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase DNA probe, primers, and oligonucleotides and the transgenic animal containing DNA encoding telomerase are not disclosed as capable of use together.

Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the telomerase DNA probe, primers, and oligonucleotides and the mouse having endogenous telomerase gene disrupted are not disclosed as capable of use together.

Invention IV and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the telomerase DNA probe, primers, and oligonucleotides are not used in the method of treating cancer.

Inventions IV and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the telomerase DNA probe, primers, and oligonucleotides are not used in the method of identifying an effector of telomerase activity.

Inventions of Groups V-VIII, X and XI are unrelated. The inventions of Group V, VI and X are independent methods having different steps and product. The transgenic animal of groups VII and VIII is not used in any of the methods of Groups V, VI, X and XI.

Group IX and X are related as a product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, i.e. an inhibitor of vertebrate telomerase may be use in other process, such as inhibition of telomerase reaction *in vitro*.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species election

This application contains claims directed to the following patentably distinct species of the claimed invention:

18 sequences of DNA encoding human telomerase or its variants,
SEQ ID NO:1, 34-38, 41, 43, 45, 47, 49, 51, 55, 63, 67, 71, 75, 79, 83.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 43 and 53 are generic.

The application also contains claims directed to DNA encoding:
intron Y, SEQ ID NO:18;
intron 1, SEQ ID NO:23;
intron α, SEQ ID NO:25;
intron β, SEQ ID NO:27;
intron 2, SEQ ID NO:29;
intron 3, SEQ ID NO:30;
intron X, SEQ ID NO:32, the partial sequence of genomic intron, SEQ ID NO:33.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 6, 7, 24, 37, 39, 43, 47, 48 and 61 are generic.

The application also contains claims directed to the following patentably distinct species of the claimed invention:

36 amino acid sequences of human telomerase or its variants,
SEQ ID NO: 2, 35, 37, 39, 42, 44, 46, 48, 50, 52 -54, 56-58, 60-62, 64-66, 68-70, 2-74, 76-78, 80-82, 84-86.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4, 18, 34 and 53 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C. F. R. paragraph 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filled petition under 37 C.F.R. paragraph 1.48 (b) and by the fee required under CFR paragraph 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

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